

## REMARKS/ARGUMENTS

Paragraph 0021 was amended to correct an omission. The word “element” was inserted between the words “annular-shaped” and “may.” Paragraph 0049 was amended to add the serial number 10/006,400 and the filing date. Paragraph 0049 was also amended to remove the statement that the application was filed “on the same day as the present application and the reference to the attorney docket number.” The applicant thanks the Examiner for pointing out these errors.

Claims 1-37 remain in this application. Claims 1, 11, 19-23 and 25-32 were amended. Claims 38-61 were cancelled in a previous response.

Claims 1, 11 and 19 were rejected under nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,663,655. The applicant has attached a terminal disclaimer for U.S. Patent No. 6,663,655. The applicant respectfully requests that the nonstatutory obviousness-type double patenting rejections be removed from claims 1, 11 and 19.

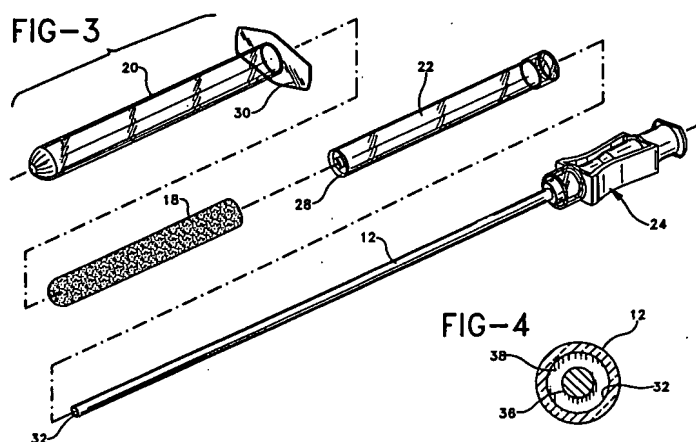
Claims 1 and 11 were amended to more clearly describe the invention. The limitation of a body having a lumen extending between the proximal end and the distal port was changed to a lumen extending between the proximal end and the distal end. The inlet port limitation was removed.

Claim 19 was also amended to more clearly describe the invention. The plug member limitation was amended to add the limitations of a distal end, a proximal end, a lumen extending between the proximal end and the distal end and the plug member lumen being in fluid communication with the elongate member lumen. Claim 20 was amended to change the limitation that the plug member comprises a passage therein extending between the distal port and the lumen to the plug member lumen extends between the plug member distal end and the elongate member distal end. Claims 21 – 23, 25 – 27 and 32 were amended to change the term passage to body member lumen. Claim 27 – 32 were amended to change the term elongate member to second elongate member and avoid confusion between the elongate member limitation of claim 19.

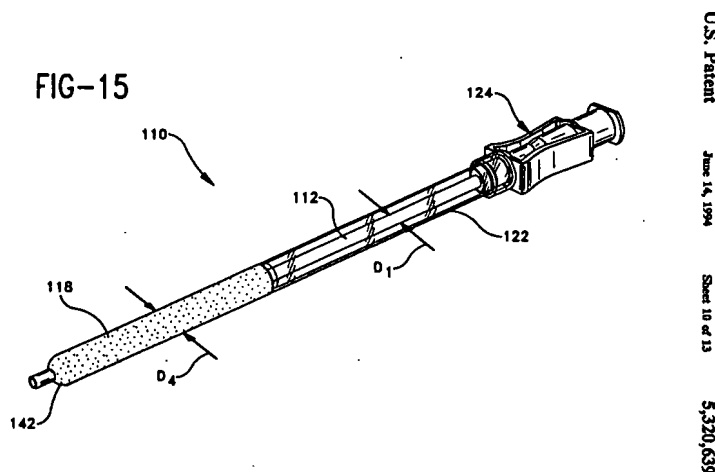
The Examiner rejected claims 1-25, 27-29, 31-35 and 37 under 35 U.S.C. §103(a) as purportedly being unpatentable over Rudnick, U.S. Patent No. 5,320,639. Claim 1 includes the limitation “a bioabsorbable body comprising a proximal end, a distal end, the body comprising a lumen extending

between the proximal end and a distal inlet port.” The Examiner contends that Rudnick discloses a vascular plug delivery system but does not disclose a bioabsorbable body that is separate from the sealing member. The Examiner argues that Rudnick discloses that the plug may be provided with a more densely packed material on the outside such that complete swelling of the plug occurs after it reaches the puncture site. The Examiner also argues that it would have been obvious to use a bioabsorbable material separate from the plug member as the densely packed material disclosed by Rudnick because the densely packed material could be made from a different material that is more dense than the sealing member. The applicant respectfully disagrees with these arguments.

In the office action, the Examiner cites a portion of the specification that specifically refers to a specific embodiment illustrated in Figure 15. However, in the Office Action, the Examiner cites the text that describes Figure 15 but states that this is illustrated in Figure 3. The Examiner goes on to argue that the sealing member is considered to be numeral 18. This interpretation seems to suggest that the body is numeral 20 in Figure 3, since claim 1 requires the sealing member to be disposed within the lumen of the body. However, Rudnick discloses that 20 is a housing that is removed from the patient. Figures 3 and 15 of Rudnick have been reproduced below for reference. The primary difference between the devices illustrated in Figures 3 and 15 is that Figure 3 illustrates the plug 18 covered by the housing 20 and Figure 15 illustrates the plug 18 alone.



U.S. Patent June 14, 1994 Sheet 3 of 13 5,320,639



In order for claim 1 to be invalid as obvious, Rudnick must teach, suggest or motivate the entire bioabsorbable body limitation. The only sentence within Rudnick that the Examiner relies upon to disclose the bioabsorbable body limitation is, "Alternatively, the plug may be provided with a more densely packed material on the outside such that complete swelling of the plug occurs after it reaches the puncture site." (Rudnick, Col. 6, lines 57-60.) The applicant submits that in the context of the Rudnick specification, this sentence does not provide the required disclosure for modifying the Rudnick device to cover a bioabsorbable body that is a separate and distinct structure from the sealing member.

The applicant submits that the sentence cited by the Examiner is directed towards a more highly compressed plug material on the outer surface that is the same material as the rest of the plug. The cited sentence refers to an embodiment, where the plug is inserted into the tissue channel without a housing that separates the plug from the tissue channel. Because the plug expands when exposed to body fluids, the expansion of the plug material must be delayed until the plug is fully inserted into the tissue channel. The applicant submits that the sentence cited by the Examiner simply states that a more densely packed or compressed outer material will not expand as quickly when exposed to fluids as a loosely packed inner material. This allows the plug to be fully inserted before the fluid absorption causes expansion of the plug.

Other than the delayed expansion, there are no other functional differences between the more densely packed material on the outside of the plug and material on the inside of the plug. Rudnick

discloses that the plug may be formed from a spongy or compressed material that expands upon contact with body moisture. The plug is preferably manufactured from a resorbable material that is absorbed by the patient's body as the wound heals such as collagen and synthetic biopolymers. (Rudnick, Col. 4, lines 3-13.) Throughout the specification, the plug material is described in the singular, indicating that the plug is fabricated from a single material. Similarly, all of the drawings within Rudnick illustrate the plug as being a single piece structure made of a single material. For these reasons, the applicant respectfully submits that Rudnick does not disclose or suggest an outer surface that is made from completely different material than the inner plug.

Because Rudnick discloses a single material plug, the bioabsorbable body having a lumen claim limitation is not disclosed. The applicant submits that because the plug limitation is not disclosed by Rudnick, claim 1 is not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick. Claims 2-10 depend from claim 1 and for the same reasons are not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick.

Like claim 1, claim 11 includes the limitations of a bioabsorbable body having a lumen and a sealing member disposed within the lumen. For the same reasons discussed above in claim 1, the applicant submits that Rudnick does not disclose a separate bioabsorbable body having a lumen. Claim 11 includes the additional limitations that the lumen comprises a tapered portion that tapers in cross-section. In the Office Action, the Examiner states that the sealing member can be said to taper and indicates that the taper is shown in Figure 3. While Rudnick may illustrate a tapered sealing member, there is no disclosure of a lumen within a bioabsorbable body or more specifically, there is no disclosure of a tapered lumen within a bioabsorbable body. Further, there is no disclosure of a sealing member that is movable into the tapered portion of the lumen. For these reasons, the applicant submits that most of the limitations of claim 11 are not disclosed by Rudnick and claim 11 is not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick. Claims 12 and 14-18 depends from claim 11 and for the same reasons discussed above, the applicant submits that claims 12 and 14-18 are not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick.

Claim 13 depends from claim 11 and includes the limitation that the sealing member comprises a coil of material. The Examiner argues that the sealing member 19 can be considered a coil of material as shown by the dark lines in Figure 2. (Office Action, Page 6.) The applicant submits that Figure 2 is a

cross sectional drawing and the dark diagonal lines are hatchings used to indicate that the cross section of the plug is illustrated. As required under 37 CFR 1.84(h)(3), sectional views must have hatching to indicate the section portions of the drawing. These hatchings are not indicative of a structure. Thus, the applicant submits that Rudnick does not disclose a sealing member that comprises a coil of material. For these reasons and the reasons discussed above in claim 11, the applicant submits that claim 11 is not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick.

Claim 19 was amended to more clearly describe the invention. The limitation of a plug member port in communication with an elongate member lumen was changed to a plug member having a distal end, a proximal end, a lumen extending between the proximal end and the distal end and the plug member lumen being in fluid communication with the elongate member lumen. The limitation of a plug member having a cross section larger than the cross section of the elongate member was removed.

Claim 19 includes the limitation of the plug member lumen being in fluid communication with the elongate member lumen. With reference to Figure 15, the Rudnick device includes a plug 118 that is mounted around a cannula 112 that extends through the entire length of the plug 118. The applicant submits that Rudnick discloses that fluid from the patient travels through the cannula 112 directly and fluid does not contact any portion of the plug. Thus, the applicant submits that Rudnick does not disclose fluid communications between the plug 118 and the cannula 112. For these reasons, Rudnick does not disclose the limitation of the plug member lumen being in fluid communication with the elongate member lumen. Thus, the applicant respectfully submits that claim 19 is not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick.

Claim 20 depends from claim 19 and for the reasons discussed in claim 19, the applicant submits that claim 20 is not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick.

Claim 21 includes the limitation of a sealing member disposed in the plug member lumen. As discussed above in claim 1, the applicant argues that Rudnick does not disclose or suggest an outer surface that is made from completely different material than the inner plug. Thus, Rudnick does not disclose the limitation of claim 21, a sealing member disposed in the plug member lumen for substantially sealing the plug member lumen from fluid flow. The applicant submits that for the same reasons discussed above in claim 1 and claim 19, claim 21 is not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick. Claims 22-23 depend from claim 21 and for the same reasons discussed

above, the applicant submits that claims 22 and 23 are not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick.

Claim 24 depends from claim 21 and includes the limitation that the sealing member comprises a valve. The Examiner argues that the reference number 24 illustrated in the figures is considered to be a valve connected to the sealing member. Rudnick discloses that the hub assembly in the figures is reference number 24. The applicant submits that claim 21 requires that the sealing member be disposed in the plug member lumen. In contrast, the hub assembly disclosed in Rudnick is located on the proximal end of the vascular plug delivery mechanism and not in the plug member lumen. For these reasons and the reasons discussed above in claim 21, the applicant submits that claim 24 is not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick.

Claim 25 depends from claim 21 and includes the limitation that the plug member lumen includes a tapered portion reducing in cross-section, and wherein the sealing member comprises a generally annular-shaped member disposed adjacent a wide end of the tapered portion of the plug member lumen, the annular-shaped being movable into the tapered portion for substantially sealing the plug member lumen. This limitation is similar to the limitations of claim 11. As discussed above in claim 1 and 11, the applicant submits that Rudnick does not disclose a sealing member that is separate from the plug member or a sealing member that is movable into the tapered portion of the lumen. For these reasons, the applicant submits that claim 25 is not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick.

Claim 26 depends from claim 21. In the Office Action, the Examiner states that claim 26 would be allowable if rewritten in independent form. (Office Action, page 6.) The applicant thanks the Examiner for this allowability of this claim and submits that claim 26 is allowable based upon the Examiner's statement and the reasons discussed above in claim 21.

Claims 27 – 29 and 31- 32 depend from claims 19 and 20. For the same reasons discussed above in claim 20, the applicant submits that claims 27- 32 are not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick. Claims 33 – 35 and 37 depend from claim 19 and for the same reasons discussed above in claim 19, the applicant submits that claims 33 – 37 are not invalid as obvious under 35 U.S.C. §103(a) in view of Rudnick. In the Office Action the Examiner stated that claims 30 and 36 would be

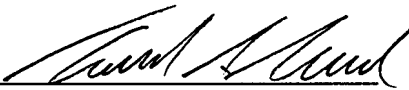
allowable if rewritten in independent form. The applicant submits that claims 30 and 36 are allowable as acknowledged by the Examiner and for the reasons discussed above in claims 19 and 20.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned collect at (415) 705-6377 if there are any outstanding issues or questions which can be resolved to allow this application to be passed to issue.

Respectfully submitted,

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